NIAID CLINICAL RESEARCH STANDARDS

The NIAID Clinical Research Standards provide a framework to promote scientifically sound and ethically responsible research. The Standards are grouped into four key areas:

1. Clinical Research Development, Review, Conduct and Oversight;
2. Clinical Research Management;
3. Training and Education; and
4. Quality Assurance/Quality Control.

While this framework defines requirements for maximizing the quality of NIAID clinical research, it also provides flexibility to account for the diverse contexts in which NIAID research is conducted.

The scope of these standards includes all clinical research activities as defined by the 1995 NIH Director's Panel on Clinical Research:

> "(a) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. This area of research includes:
> - mechanisms of human disease;
> - therapeutic interventions;
> - clinical trials; and
> - development of new technologies.

> (b) Epidemiologic and behavioral studies
> (c) Outcomes research and health services research.
>
> Excluded from this definition are in vitro studies that utilize human tissues but do not deal directly with patients. In other words, clinical or patient-oriented research is research in which it is necessary to know the identity of the patients from whom the cells or tissues under study are derived."

1. CLINICAL RESEARCH DEVELOPMENT, REVIEW, CONDUCT AND OVERSIGHT

STANDARD 1.1

Each Division will have established protocol development and implementation tools [e.g., templates for protocols, informed consent, manual of operations, standard operating procedures (SOPs), case report forms and safety reports].

PURPOSE: To assist investigators in developing quality clinical research protocols in accordance with applicable regulations and guidance.

RELATED NIAID POLICY DOCUMENTS:

- See NIAID Protocol Template Guidance

STANDARD 1.2

Each Division will have policies and/or standard operating procedures, for:

- **Scientific review (including biostatistical review)**
- **Regulatory review**
- **Institutional Review Board/Ethics Committee review**
- **Conflict of Interest review**
- **Medical Monitoring**
- **Data and Safety Monitoring review including trial-specific study progress and safety monitoring plans to be submitted by the study team for Division approval, and**
- **Study participant outreach.**

PURPOSE: To ensure regulatory compliance and reduce risks to subjects: scientific review ensures scientific quality, the importance to clinical practice, and the appropriateness of the study to the sponsoring entity; IRB/EC review ensures study participant safety and good ethical conduct of the study; Conflict of Interest reviews help to minimize bias and ensure the public trust in government-sponsored research; independent monitoring is essential for all clinical trials involving investigational drugs, devices, or biologics and other clinical research, including research of licensed products, perceived to involve more than a minimal risk; Data and Safety Monitoring Boards and Safety Monitoring Committees are essential to monitor study participant safety and evaluate the efficacy of the intervention; research participants involvement in clinical research development promotes sound ethical science.

RELATED NIAID POLICY DOCUMENTS:

- See NIAID Data and Safety Monitoring Board Principles

2. CLINICAL RESEARCH MANAGEMENT

STANDARD 2.1

Each Division will have policies and/or SOPs for site establishment, approval of study initiation and for initial and ongoing site evaluation including minimal standards for operations (e.g., site staffing, training, facilities, data management, pharmacy management, specimen handling, record keeping and safety reporting).

PURPOSE: To ensure that sites are qualified and ready to perform a particular NIAID funded clinical research study.

STANDARD 2.2

Each Division will have policies/SOPs that describe their requirements for clinical data management system/infrastructure including policies/SOPs for data collection, data integrity, and data security.

PURPOSE: To ensure that the results of research are carefully recorded in a form that will allow accuracy and access for analysis and review.

STANDARD 2.3

Each Division will have policies/SOPs that specify safety reporting procedures including Adverse Events/ Serious Adverse Events/Unexpected Events reporting. These reporting policies/SOPs should be specific in definitions/categorizations of events, use of specific required forms, timing of reports, and identification of specific accountability for submission, review and follow up action.

PURPOSE: To ensure that mechanisms and procedures are in place to protect the safety of participants in NIAID-supported clinical research.

3. *TRAINING AND EDUCATION*

STANDARD 3.1

Each Division will establish minimal standards for training Division staff and clinical site staff in good clinical practice (GCP), human subjects protection (HSP), good laboratory practice (GLP) and relevant Institute and Division policies.

PURPOSE: To communicate the expectations of acceptable practice in conducting clinical research and human subject protections.

4. QUALITY ASSURANCE/QUALITY CONTROL

STANDARD 4.1

Each Division will have policies to ensure that quality assurance and quality control processes are established in their Division and clinical research sites.

PURPOSE: To ensure adherence to relevant clinical research-related laws and regulations as well as NIH, NIAID, and Division policies and standards; and to identify and resolve problems at their early stages.